

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE: TRICOR INDIRECT PURCHASER  
ANTITRUST LITIGATION

Civil Action No.: 05-360 (KAJ)  
(Consolidated)

THIS DOCUMENT RELATES TO:

ANSWER BY FOURNIER

C.A. No. 05-360 (KAJ)  
C.A. No. 05-365 (KAJ)  
C.A. No. 05-390 (KAJ)  
C.A. No. 05-394 (KAJ)  
C.A. No. 05-426 (KAJ)  
C.A. No. 05-450 (KAJ)  
C.A. No. 05-467 (KAJ)  
C.A. No. 05-475 (KAJ)  
C.A. No. 05-482 (KAJ)  
C.A. No. 05-516 (KAJ)  
C.A. No. 05-695 (KAJ)

**FOURNIER'S ANSWER TO THE END PAYOR PLAINTIFFS CONSOLIDATED  
CLASS ACTION COMPLAINT**

Respondents, Fournier Industrie et Santé and Laboratoires Fournier S.A. (collectively, "Fournier"), by their undersigned attorneys, answer to End Payor Plaintiffs' ("End Payors") Consolidated Class Action Complaint ("End Payor Complaint"), on knowledge as to themselves and otherwise on information and belief, as follows:

1. Admitted that Fournier manufactures a fenofibrate drug product marketed by Abbott under the trade name TriCor, and that Abbott's sales of TriCor exceeded \$750 million in 2004. To the extent paragraph 1 contains a description of this proceeding and conclusions of law, no response is required. Otherwise denied.

2. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

3. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

4. To the extent that End Payors' averments state legal conclusions, no response is required. To the extent End Payors' averments intend to recite from unidentified Fournier documents, the documents speak for themselves. Otherwise denied.

5. Admit that plaintiffs do not challenge Abbott's and Fournier's right or ability to apply to the FDA for approval of new fenofibrate formulations. Otherwise denied.

6. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

7. Denied.

8. Denied.

9. To the extent paragraph 9 contains a description of this proceeding and conclusions of law, no response is required. Otherwise denied.

10. To the extent paragraph 10 contains a description of this proceeding and conclusions of law, no response is required. Otherwise denied.

11. To the extent paragraph 11 contains a description of this proceeding and conclusions of law, no response is required. Otherwise denied.

12. To the extent paragraph 12 contains a description of this proceeding and conclusions of law, no response is required. Otherwise denied.

13. To the extent paragraph 13 contains a description of this proceeding and conclusions of law, no response is required. Otherwise denied.

14. Admitted that this court has jurisdiction over the alleged subject matter of this litigation.

15. Denied.

16. Admitted that End Payors' purport to bring this action on behalf of themselves and other similarly situated and purport to define a class but deny that class treatment is proper in this case. Otherwise denied.

17. Admitted Fournier manufactures TriCor and that Abbott markets, sells, and ships Tricor across state lines to United States customers. Fournier is without sufficient information or knowledge to form a belief as to the truth of the remaining averments in paragraph 17, and, therefore, denies these allegations. To the extent that End Payors' averments state legal conclusions, no response is required.

18. Fournier is without sufficient information or knowledge to form a belief as to the truth of the remaining averments in paragraph 18, and, therefore, denies these allegations.

19. Denied.

20. Fournier is without sufficient information or knowledge to form a belief as to the truth of the remaining averments in paragraph 20, and, therefore, denies these allegations.

21. Denied.

22. Admitted.

23. Admitted.

24. Denied.

25. Admitted.

26. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

27. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

28. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

29. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

30. To the extent that End Payors' averments intend to recite from cited documents, those documents speak for themselves. Otherwise denied.

31. To the extent that End Payors' averments intend to recite from a cited document, the document speaks for itself. Otherwise denied.

32. To the extent that End Payors' averments intend to recite from a cited document, the document speaks for itself. Otherwise denied.

33. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

34. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

35. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

36. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

37. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

38. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

39. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

40. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

41. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

42. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

43. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

44. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

45. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

46. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

47. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

48. Admitted that paragraph 48 provides a non-exhaustive description of fenofibrate

49. Admitted.

50. Admitted that Novopharm filed an ANDA with the FDA on or about December 14, 1999 for fenofibrate capsules; Novopharm submitted a Paragraph IV certification; and that Novopharm subsequently amended that ANDA. To the extent that End Payors' averments intend to recite the ANDA and Paragraph IV certification, those documents speak for themselves. Otherwise denied.

51. Admitted.

52. Admitted that on April 7, 2000, Abbott and Fournier sued Novopharm in the United States District Court for the Northern District of Illinois for infringement of the '726 Patent; that in April 2000, and Abbott and Fournier sued Impax for infringement of the '726

Patent. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

53. Admitted that on December 10, 1999, Abbott filed NDA No. 021203 for 54 mg and 160 mg fenofibrate tablets, which the FDA approved on September 4, 2001, and that Abbott sought and obtained from the FDA an additional indication for the TriCor tablet formulation that the capsule formulation did not have, and in support of that application Abbott relied on clinical studies conducted in connection with the capsule formulation. Otherwise denied.

54. Admitted that Abbott discontinued marketing the TriCor original tablet formulation after the new tablet formulation became available and that Abbott communicated the discontinuance of the TriCor capsule formulation to First DataBank, Inc., the company that provides the NDDF. Otherwise denied.

55. Admitted that Abbott stopped detailing the capsule formulation and destroyed part of its existing capsule inventory after discontinuing the capsule product. Otherwise denied.

56. Admitted that on March 19, 2002, U.S. District Court of the Northern District of Illinois granted summary judgment of non-infringement in favor of Teva, and that on March 26, 2003, that court granted summary judgment of non-infringement in favor of Impax. Otherwise denied.

57. Admitted that Teva received final FDA approval to market its 200 mg and 134 mg fenofibrate capsule products and tentative FDA approval to market its 67 mg fenofibrate

capsule products on April 9, 2002; and that Teva purports to have begun selling its 200 mg and 134 mg fenofibrate capsule products in April 2002. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

58. Fournier is without sufficient information or knowledge to form a belief as to the truth of whether the fenofibrate capsules Teva shipped to its customers were returned, and therefore denies these allegations. Otherwise denied.

59. Admitted that on October 27, 2003, the FDA granted Impax final approval to market its fenofibrate capsule products. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

60. Admitted that on June 17, 2002, Teva file with the FDA an ANDA for its fenofibrate 54 mg and 160 mg tablets, Teva submitted a Paragraph IV certification, and that Teva sent Abbott a Paragraph IV certification dated August 21, 2002. Otherwise denied.

61. Admitted that Abbott and Fournier filed patent infringement action Civil Action No. 02-1512 against Teva for infringement of the '736 Patent, the '670 Patent, and the '405 Patent, and that Teva provided samples and technical details of its fenofibrate tablets to Abbott and Fournier. Otherwise denied.

62. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

63. Admitted.

64. Admitted.



65. Admitted

66. Admitted that on August 29, 2003, Abbott and Fournier filed a patent infringement action Civil Action No. 03-847 against Teva for infringement of the '552 Patent. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

67. Admitted that on October 29, 2003, Abbott submitted NDA No. 021656 to the FDA for its new formulation of TriCor fenofibrate tablets in 48 mg and 145 mg dosage forms. Otherwise denied.

68. Admitted.

69. Admitted.

70. Admitted.

71. Admitted that on January 22, 2004, Abbott and Fournier filed a patent infringement action Civil Action No. 04-0047 against Teva for infringement of the '881 Patent. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

72. Admitted that on March 5, 2004, the FDA granted tentative approval to Teva's Tablet ANDA. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

73. Admitted that on or around November 5, 2004, Abbott received FDA approval to market 145 mg and 48 mg fenofibrate tablets. Otherwise denied.

74. Denied.

75. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

76. Admitted that on May 6, 2005, the Court ruled that Teva's tablet product does not infringe the '552 Patent, the '670 Patent, or claim 9 of the '405 Patent. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

77. Admitted.

78. Admitted that Abbott and Fournier sent a letter to the Court dated May 16, 2005. To the extent Teva's averments intend to summarize Abbott and Fournier's May 16, 2005 letter to the Court, the document speaks for itself. Otherwise denied.

79. Admitted that on June 8, 200, Abbott announced that it had settled its patent dispute with Teva. To the extent End Payors' averments intend to recite a cited document, that document speaks for itself. Otherwise denied.

80. Admitted.

81. Denied.

82. Admitted that Abbott is the licensee from Fournier of the '726 Patent, the '670 Patent, the '405 Patent, the '552 Patent, and the '881 Patents. Otherwise denied.

83. To the extent that End Payors' averments intent to recite Teva's Amended Counterclaims and an unidentified Reginault document, those documents speak for themselves. Otherwise denied.

84. Denied.

85. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

86. Denied.

87. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

88. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

89. Admitted that Teva is producing and marketing a branded fenofibrate product under the Lofibra trade name. Fournier is without sufficient information or knowledge to form a belief as to the truth of Teva's sales, customer returns, or business, and therefore denies these allegations. Otherwise denied.

90. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

91. Denied.

92. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

93. Admitted that the new TriCor tablet formulation, unlike the original tablet formulation, does not need to be taken with food, and that data indicated that roughly one-third

of patients were not compliant in taking the original tablet formulation with food as directed. Otherwise denied.

94. To the extent that End Payors' averments intent to recite a website, that website speaks for itself. Otherwise denied.

95. To the extent that End Payors' averments intent to recite a website, that website speaks for itself. Otherwise denied.

96. To the extent that End Payors' averments intent to recite a website, that website speaks for itself. Otherwise denied.

97. Denied.

98. To the extent that End Payors' averments state legal conclusions, no response is required. Otherwise denied.

99. Admitted that plaintiffs purport to bring this action on behalf of themselves and others similarly situated and purport to define a class but deny that class treatment is proper in this case. Otherwise denied.

100. Denied

101. Denied

102. Denied

103. Fournier is without sufficient information or knowledge to form a belief as to the truth of whether plaintiffs' counsel are experienced in antitrust and consumer class action litigation, and therefore denies these allegations. Otherwise denied.

104. Denied.

105. Denied.

106. Denied.

### **COUNT I**

107. Fournier repeats and realleges its responses herein to paragraphs 1-106 in answer to paragraph 107.

108. Denied.

109. Denied.

110. Admitted that End Payors purport to seek equitable and injunctive relief. Otherwise denied.

### **COUNT II**

111. Fournier repeats and realleges its responses herein to paragraphs 1-110 in answer to paragraph 111.

112. Denied.

113. Denied.

114. Admitted that End Payors purport to seek damages. Otherwise denied.

**COUNT III**

115. Fournier repeats and realleges its responses herein to paragraphs 1-114 in answer to paragraph 115.

116. Denied.

117. Denied.

**COUNT IV**

118. Fournier repeats and realleges its responses herein to paragraphs 1-117 in answer to paragraph 118.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

**COUNT V**

123. Fournier repeats and realleges its responses herein to paragraphs 1-122 in answer to paragraph 123.

124. Denied.

125. Denied.

**FIRST AFFIRMATIVE DEFENSE**

Plaintiffs fail to state a claim against Fournier upon which relief may be granted.

**SECOND AFFIRMATIVE DEFENSE**

Plaintiffs have not suffered, and will not suffer, injury of the type that the antitrust laws are designed to prevent, or any other injury to a legally cognizable interest, by reason of the conduct alleged in the End Payors' Complaint.

**THIRD AFFIRMATIVE DEFENSE**

At all times, Fournier has acted in good faith in furtherance of its legitimate business interests and has caused no injury to competition, the public, or plaintiffs.

**FOURTH AFFIRMATIVE DEFENSE**

Fournier's conduct is protected under the Noerr-Pennington doctrine and/or otherwise under the Constitution of the United States.

**FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are precluded, in whole or in part, by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984 and related amendments.

**SIXTH AFFIRMATIVE DEFENSE**

To the extent there is a finding of conduct that prevented generic entry and higher prices as a result, plaintiffs' claims are barred, in whole or in part, to the extent any higher prices were passed on, in whole or in part, to parties not included in the putative class.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because plaintiffs would be unjustly enriched if allowed to recover all or any part of the damages alleged in the End Payors' Complaint

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims fail to comply with the pleading requirements of Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

**NINTH AFFIRMATIVE DEFENSE**

Plaintiffs did not suffer injury or damages by reason of any act or omission by Fournier.

**TENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because plaintiffs failed to mitigate their damages.



**ELEVENTH AFFIRMATIVE DEFENSE**

Any injuries, losses, or damages suffered by plaintiffs were proximately caused by their own actions regardless of whether contributory, negligent, incompetent, careless or reckless.

**TWELFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because plaintiffs alleged damages, if any, are speculative.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Venue does not lie in this district as to the claims against Fournier.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Fournier does not maintain monopoly power in the relevant market.

**FIFTEENTH AFFIRMATIVE DEFENSE**

The Food and Drug Administration approved each version of TriCor for sale in the United States.

**SIXTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because this action is not properly maintainable as a class action.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because there have been no classwide damages as alleged by plaintiffs.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because they contravene the rule of law established by the United States Supreme Court in Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977).

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the applicable statute of limitations and/or laches.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because of waiver and/or estoppel.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Fournier reserves the right to add to its affirmative defenses as additional information becomes available in the course of this litigation.

**RELIEF REQUESTED**

WHEREFORE, Fournier, having answered, respectfully requests judgment dismissing with prejudice the End Payor Complaint and each and every claim for relief therein,

and awarding Fournier its costs, disbursements, attorneys' fees and such other and further relief as the Court deems just and proper.

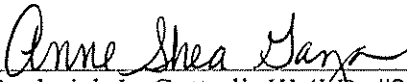
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Dated: July 21, 2006



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**CERTIFICATE OF SERVICE**

I hereby certify that on July 21, 2006, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on July 21, 2006, I sent by electronic mail the foregoing document to the following non-registered participants:

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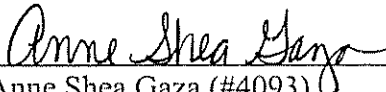
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